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06/482,402

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
06/482,402	06/07/98	UNRECORDED	

EXAMINER

HENRY H. NIXON
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WASHINGTON DC 20004

ART UNIT	PAPER NUMBER
1642	17

DATE MAILED: 09/15/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on July 24, 1998
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-15 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 11-15 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Response Due - 15 Dec. 1998
Response Due 15 Jan 1999
w/F1 A.F.
Response Due 15 Feb 1999
w/F2 A.F.
Response Due 15 March 1999
w/F3
A.F.
NONEXTENDABLE
File Continuation or
Notice of Appeal

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1. The Amendment filed July 21 1998 (Paper No.16 in response to the Office Action of January 21, 1998 (Paper No. 12) is acknowledged and has been entered. Claims 11-15 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. It is noted that Applicant regrets Examiner's decision to make the Restriction Requirement final and restates the arguments previously disclosed. The arguments have been noted but have not been found persuasive for the reasons previously disclosed on page 2 in both Paper Nos 8 and 12. Applicant further argues that (a) there is no logical or technical basis for requiring the restriction of claims designated in the parent application as falling within a single Examiner-identified Group and (b) all of the claims in Group IV share Class and Subclass designations therefore search and examination of the entire Group can be made without serious burden. The arguments have been noted but have not been found persuasive because (a) of the logical and technical reasons disclosed in Paper No. 8, Section 2, page 2 and further, review of the Restriction Requirement of September 15, 1994 in the parent application USSN 08/196,082 clearly reveals that Group IV is drawn to DNA encoding Thyroid peroxidase, vector and host and therefore it would appear that the inclusion of claim 28, drawn to a DNA sequence encoding a peptide which binds to the B-cell epitope of thyroid peroxidase was an inadvertent typographical error (b) classification of subject matter is merely one indication of the burdensome nature of the search involved and the literature search, particularly relevant in this art, is not coextensive and is much more important than classification in evaluating the burden of search because different searches and issues are involved in the

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examination of each group. For these reasons the restriction requirement is deemed to be proper and the finality of the previous restriction requirement is maintained.

Specification

4. The specification on page 1 should be amended to reflect the status of the parent applications.

Oath/Declaration

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

The newly submitted oath or declaration is defective because:
The residence and post office address of Inventor Rapoport were lined through and changed without being initialed.

Acknowledgement is made of applicant's claim for priority based on PCT applications PCT/US92/06283 filed 30 July 1992 and PCT/US92/07381 filed 28 August 1992. It is noted however, that applicant have not filed a certified copy of the priority documents as required by 35 USC 119.

6. The objections recited in Paper No. 12, Sections 5, 6, 7 and 8 are being maintained.

Applicant requests that these objections be held in abeyance pending notification of allowable subject matter. The objections will be held in abeyance but will be maintained because amendments addressing these objections have not been submitted.

7. The following rejections are being maintained:

Claim Rejections - 35 USC § 112

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8. Claims 11-14 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 12, Section 12, pages 5-6.

Applicant argues that (a) the specification teaches examples and methods of screening that would enable a person of ordinary skill to practice the invention since DNA sequences useful according to the invention may be selected for testing and evaluation in the ordinary course of laboratory efforts in the pertinent field, (b) because Dr. Rapoport was the first to describe truncated, secretable forms of human thyroid peroxidase his pioneering work is entitle to a broad scope of protection commensurate wit the fact that he has described and enabled the production and practical application of secretable human thyroid peroxidase. The arguments have been noted but have not been found persuasive because (a and b) although the specification clearly teaches site directed mutagenesis of a stop codon immediately upstream of the putative transmembrane domain to convert hTPO from membrane bound to a soluble version that is immunologically and enzymatically active and immunologically intact (see p. 8, lines 27- page 9 line 6) and teaches assays to demonstrate the immunological and enzymatic activity of the soluble hTPO (see pages 58-60) there are no parameters described and no teaching of how to determine which sites are appropriate for mutation so that DNA sequences could be made and then selected for testing and evaluation to determine if the mutated, expressed protein will be soluble and function as claimed. The single example of a mutated thyroid peroxidase is not sufficient enablement for Applicant's broadly claimed invention. The claims as broadly written appear to be an invitation to experiment. Applicant's attention is directed to Brenner v. Manson, 383, U.S. 519, 148 USPQ 689 wherein the court held that "a patent is not a hunting license".

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Applicant's arguments have not been found persuasive and the rejection is maintained.

9. Claims 11-15 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As drawn to (b), Applicant argues that the language is definite and will be understood by a person of ordinary skill. The argument has been noted but has not been found persuasive for the reasons previously disclosed in Paper No. 12, Section 13, page 7. The rejection of the claim can be obviated by amending the claim to read "A recombinant DNA sequence encoding a human thyroid peroxidase.....".

Claim Rejections - 35 USC § 103

10. Claims 11-15 remain rejected under 35 USC 103 for the reasons previously set forth in Paper No. 12, Section 16, pages 9-11.

Applicant argues that (a) none of the secondary references satisfy the failings of the primary references and that none of the references, alone or in combination provides the suggestion to combine required to state a proper *prima facie* obviousness rejection and (b) Examiner has used improper hindsight to supply the missing suggestion to combine which Examiner has not found in any of the primary or secondary references. The argument has been noted but has not been found persuasive because Applicant has not presented any arguments to explain why the secondary references do not satisfy the failings of the primary reference or why none of the references alone or in combination provides the suggestion to combine required to state a proper *prima facie* obviousness rejection (b) Some degree of hindsight is permissible in making rejections under 35 USC 103, however, at the

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time the invention was made (a) the DNA sequence of human thyroid peroxidase was well known as demonstrated by Seto and Libert, (b) the production of secreted proteins by transfecting host CHO cells with cDNA encoding truncated protein (wherein the hydrophilic carboxyl-terminus is deleted) and the advantages of secreted proteins were well known as demonstrated by EP 0139417 and Rose et al, (c) structural analysis of porcine thyroid peroxidase revealed a carboxyl-terminal transmembrane domain consistent with the cellular location of a putative membrane anchor as demonstrated by Magnusson et al, (d) expression vectors were well known as demonstrated by Lee et al and Ellis et al. Clearly the combined references teach not only the suggestion but also the means and motivation to successfully produce a recombinant DNA encoding a secretable thyroid peroxidase for the reasons disclosed in Paper No.12, Section 16, page 10. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference and it is not that the claimed invention must be expressly suggested in any one or all of the references; but rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

11. All other objections and rejections recited in Paper No. 12 are withdrawn.
12. No claims allowed.
13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

**A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS
FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF**

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THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached at (703) 308-2731. The fax phone number for this Art Unit is (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 USC 132 or which otherwise require a signature may be used by the applicant and should be addressed to lila.feisee@uspto.gov.

All internet e-mail communications will be made of record in the application file. **PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of USC 122.** This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and

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Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar

September 4, 1998



LILA FEISEE
SUPERVISORY PATENT EXAMINER